

Serial No.: 10/729,114

Confirmation No.: 3162

Filed: 5 December 2003

For: WOUND DRESSINGS AND METHODS

Remarks

The Office Action mailed June 29, 2010 has been received and reviewed. Claims 1, 19, and 20 having been amended, and claim 18 having been cancelled herein, the pending claims are claims 1, 2, 5-12, 14-17, and 19-28. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the amended claims can be found throughout Applicants' specification, and specifically at, for example, page 19, lines 3-28. Entry and consideration of the claim amendments are requested.

Double Patenting Rejection

Claims 1, 2, 5-12, and 14-30 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 of copending U.S. Pat. Appl. Ser. No. 10/728,577, and claims 94 and 96-117 of copending U.S. Pat. Appl. Ser. No. 10/728,439. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claim 18 under 35 U.S.C. §112, first paragraph. Although Applicants do not agree, claim 18 has been cancelled, thereby rendering this rejection moot. This has been done solely in the interest of expediting prosecution. Applicants reserve the right to present arguments at a later date (e.g., in a continuing application).

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-2, 5-8, 12, 14-18, 20, 21, and 23-28 under 35 U.S.C. §103 as being unpatentable over Cilento et al. (EP 0512855) in view of Lykke (WO 02/066087). The Examiner rejected claims 9-11, 19, and 22 under 35 U.S.C. §103 as being unpatentable over Cilento et al. (EP 0512855) in view of Lykke (WO 02/066087) and further in view of

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“SALCARE® SC95” by Ciba®. Independent claims 1, 19, and 20 having been amended, these rejections are rendered moot. Insofar as the rejections apply to the presently pending claims, they are respectfully traversed.

There is no teaching or suggestion in the combination of documents of a wound dressing (as recited, for example, in claim 1) comprising an apertured liquid permeable substrate and an absorbent, nonadherent polymer composition coated on or impregnated in the substrate; wherein in the areas where the composition is in contact with the substrate, the wound dressing includes substrate apertures that are unobstructed by the polymer composition; and wherein the absorbent, nonadherent polymer composition comprises: a hydrophobic organic polymer matrix; 1 wt-% to 60 wt-% hydrophilic organic microparticles, which when in a nonhydrated form have an average particle size of 10 microns or less; and mineral oil; wherein the polymer matrix, microparticles, and mineral oil are present in the polymer composition in an amount effective to render the composition sufficiently nonadherent such that when coated on a substrate the nonadherent polymer composition displays a 180° peel strength from stainless steel of less than 1 N/cm.

The combination of Cilento et al. and COLOPLAST does not teach or suggest Applicants' invention. The Cilento et al. patent is directed to a wound filler described as a “doughy mass” (see, for example, page 3, line 56 and page 5, line 46) or a “dough-like mass” (see, for example, page 4, line 31). The wound filler includes a polymer matrix that is sponge-like or includes a network of polymeric stretchable fibers. The polymeric matrix is a stretchable, elastic, sponge-like network (see, for example, page 2, lines 50-53). It is formed into a “flexible sheet or slab” (see, for example, page 3, line 57). There is no teaching or suggestion that this doughy mass could be coated on or impregnated into an apertured substrate to form a wound dressing, wherein in the areas where the composition is in contact with the substrate, the wound dressing includes substrate apertures that are unobstructed by the polymer composition. There is no teaching or suggestion in the cited documents how one would apply the “doughy mass” of Cilento et al. to an apertured substrate and not block or obstruct the apertures.

At pages 14 and 15 of the current Office Action, the Examiner alleged that the 4x4 dressing referred to at page 10, lines 11-12 of Cilento et al. is an “apertured gauze material” and

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that the dough “can be applied on a substrate in discrete locations, or islands so not obstructed the substrate totally.” It is not clear where in Cilento et al., the 4x4 dressing is identified as an “apertured gauze material” or that the dough can be applied on such “gauze” material in “discrete locations or islands.” The Examiner is requested to provide this information. It is respectfully submitted that the Examiner is reading more into the teaching of Cilento et al. than is there. It is noted that the term “dressing” in this context can be in a wide variety of forms (“[h]istorically, a **dressing** was usually a piece of material, sometimes cloth, but the use of cobwebs, dung, leaves and honey have also been described. However, modern dressings include gauzes (which may be impregnated with an agent designed to help sterility or to speed healing), films, gels, foams, hydrocolloids, alginates, hydrogels and polysaccharide pastes, granules and beads”, see, [http://en.wikipedia.org/wiki/Dressing_\(medical\)](http://en.wikipedia.org/wiki/Dressing_(medical)) (Exhibit A). The reference to page 10, lines 11-12 of Cilento et al., in combination with the other cited documents, is not sufficient to teach or suggest that this doughy mass could be coated on or impregnated into an apertured substrate to form a wound dressing, wherein in the areas where the composition is in contact with the substrate, the wound dressing includes substrate apertures that are unobstructed by the polymer composition.

Although Cilento et al. disclose the use of mineral oil in combination with particles, the particles are not of the size claimed. Although COLOPLAST mentions the use of mineral oil and microparticles in adhesive compositions, there is no teaching or suggestion of nonadherent compositions including mineral oil and hydrophilic organic microparticles. Thus, there is no teaching or suggestion in the combination of documents of (as recited, for example, in claim 1) a wound dressing comprising an apertured liquid permeable substrate and an absorbent, nonadherent polymer composition coated on or impregnated in the substrate; wherein in the areas where the composition is in contact with the substrate, the wound dressing includes substrate apertures that are unobstructed by the polymer composition; and wherein the absorbent, nonadherent polymer composition comprises: a hydrophobic organic polymer matrix; 1 wt-% to 60 wt-% hydrophilic organic microparticles, which when in a nonhydrated form have an average particle size of 10 microns or less; and mineral oil; wherein the polymer matrix, microparticles,

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and mineral oil are present in the polymer composition in an amount effective to render the composition sufficiently nonadherent such that when coated on a substrate the nonadherent polymer composition displays a 180° peel strength from stainless steel of less than 1 N/cm.

Applicants reiterate that, because the Cilento et al. patent is directed to a filling material, one of skill in the art would not want to, or need to, coat it on or impregnate it into an apertured substrate. Again, the Examiner assumes the 4x4 dressing referred to in Cilento et al. at page 10, lines 11-12 is a 4x4 “gauze” (see pages 17 and 19 of the Office Action). It is not clear that this is a proper interpretation. Even if it were, the purpose of Cilento et al. is to develop a product that is placed directly into a wound. Such product is not coated on or impregnated into a substrate, wherein in the areas where the composition is in contact with the substrate, the wound dressing includes substrate apertures that are unobstructed by the polymer composition.

At pages 19-20 of the Office Action, the Examiner alleged that Applicants failed to traverse the previous rejection based on Cilento et al. (EP 0512855) in view of Lykke (WO 02/066087) and further in view of “SALCARE® SC95” by Ciba®. This is incorrect. The fact that all claims were amended in the previous response rendered all rejections, including this one, moot. This is also true in this response. However, Applicants submit that this rejection is also deficient for the same reasons as discussed above, and “SALCARE® SC95” by Ciba® does not provide that which is missing.

It is respectfully submitted that the present invention can only be considered obvious with the impermissible use of hindsight reconstruction.

In *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 75 USPQ2d (BNA) 1051 (Fed. Cir. 2005), a panel of the Court of Appeals for the Federal Circuit stated that 35 U.S.C. §103 specifically requires an assessment of the claimed invention “as a whole.” “This ‘as a whole’ assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the cited references and combined them in the claimed manner.” *Id.* at 1337, 75 USPQ2d (BNA) at 1054.

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 82 USPQ2d (BNA) 1385 (2007), the U.S. Supreme Court acknowledged the utility of this “as a whole” assessment by reiterating that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 418, 127 S. Ct. 1741, 167 L. Ed. 2d at 722, 82 USPQ2d (BNA) at 1389.

This “as a whole” instruction in 35 U.S.C. §103 prevents evaluation of the invention part by part, aided by the template of the present disclosure. Without this important requirement, an obviousness assessment might reduce an invention into its component parts, then find a reference corresponding to each component. This type of assessment would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. The U.S. Supreme Court cautioned against such analysis in *KSR*, stating, “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *Id.* at 421, 127 S. Ct. 1742, 167 L. Ed. 2d at 724, 82 USPQ2d (BNA) at 1397 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight” (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412, 141 USPQ (BNA) 549 (6th Cir. 1964)))).

Following *KSR*, in *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363, 85 USPQ2d (BNA) 1641 (Fed. Cir. 2008), the Federal Circuit emphasized that “[w]e must . . . be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.” *Id.* at 1373, 85 USPQ2d (BNA) at 1648. In *Innogenetics*, conclusory assertions that it would have been obvious to a person of ordinary skill to combine prior art references was held to be vague and not helpful “in avoiding the pitfalls of hindsight that belie a determination of obviousness.” *Id.*

Reconsideration and withdrawal of these rejections are respectfully requested.

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Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of August, 2010.

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Sara E. Wigant

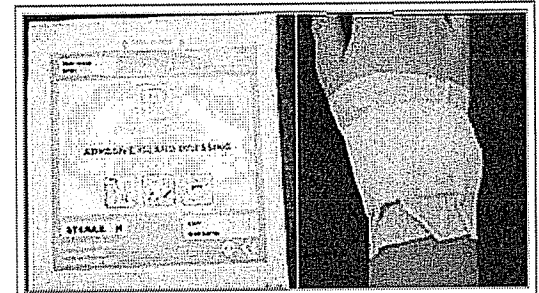
Dressing (medical)

From Wikipedia, the free encyclopedia

A **dressing** is an adjunct used by a person for application to a wound to promote healing and/or prevent further harm. A dressing is designed to be in direct contact with the wound, which makes it different from a bandage, which is primarily used to hold a dressing in place. Some organisations classify them as the same thing (for example, the British Pharmacopoeia) and the terms are used interchangeably by some people. Dressings are frequently used in first aid and nursing.

Contents

- 1 Core purposes of a dressing
- 2 Types of dressing
- 3 Usage of dressings
- 4 References



An adhesive island dressing, in its original packaging (left) and on a person's wrist (right).

Core purposes of a dressing

A dressing can have a number of purposes, depending on the type, severity and position of the wound, although all purposes are focused towards promoting recovery and preventing further harm from the wound. Key purposes of are dressing are:

- **Stem bleeding** - Helps to seal the wound to expedite the clotting process
- **Absorb exudate** - Soak up blood, plasma and other fluids exuded from the wound, containing it in one place
- **Ease pain** - Some dressings may have a pain relieving effect, and others may have a placebo effect
- **Debride the wound** - The removal of slough and foreign objects from the wound
- **Protection from infection** and mechanical damage, and
- **Promote healing** - through granulation and epithelialisation

Types of dressing

Historically, a **dressing** was usually a piece of material, sometimes cloth, but the use of cobwebs, dung, leaves and honey have also been described. However, modern dressings^[1] include gauzes (which may be impregnated with an agent designed to help sterility or to speed healing), films, gels, foams, hydrocolloids, alginates, hydrogels and polysaccharide pastes, granules and beads. Many gauze dressings have a layer of nonstick film over the absorbent gauze to prevent the wound from adhering to the dressing. Dressings can be impregnated with antiseptic chemicals, as in boracic lint or where medicinal Castor oil was used in the first surgical dressings^[2]

In the 1960s, George Winter published his controversial research on moist healing. Previously, the accepted wisdom was that to prevent infection of a wound, the wound should be kept as dry as possible. Winter demonstrated that wounds kept moist healed faster than those exposed to the air or covered with traditional dressings.

Various types of dressings can be used to accomplish different objectives including:

- Controlling the moisture content, so that the wound stays moist or dry,
- Protecting the wound from infection,
- Removing slough, and
- Maintaining the optimum pH and temperature to encourage healing.

Occlusive dressings, made from substances impervious to moisture such as plastic or latex, can be used to increase the rate of absorption of certain topical medications into the skin.

Usage of dressings

Applying a dressing is a first aid skill, although many people undertake the practice with no training - especially on minor wounds. Modern dressings will almost all come in a prepackaged sterile wrapping, date coded to ensure sterility. This is because it will come in to direct contact with the wound, and sterility is required to fulfil the 'protection from infection' aim of a dressing.

Historically, and still the case in many less developed areas and in an emergency, dressings are often improvised as needed. This can consist of anything, including clothing or spare material, which will fulfil some of the basic tenets of a dressing - usually stemming bleeding and absorbing exudate.

Applying and changing dressings is one common task in nursing.

An "ideal" wound dressing is one that is sterile, breathable, and conducive for a moist healing environment. This will then reduce the risk of infection, help the wound heal more quickly, and reduce scarring.

References

1. ^ "www.dressings.org". SMTL. <http://www.dressings.org/>. Retrieved 2007-02-24.
2. ^ "Report upon the Use of a Mixture of Castor oil and Balsam of Peru as a Surgical Dressing". pubmedcentral. <http://www.pubmedcentral.nih.gov/pagerender.fcgi?tool=pmcentrez&pageindex=1&artid=1425429>. Retrieved 2007-01-26.

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